CLAIMS

What is claimed is:

1. A method of treating, preventing, modifying or managing pain, which comprises administering to a patient in need of such treatment, prevention, modification or management a therapeutically or prophylactically effective amount of an immunomodulatory compound, or a pharmaceutically acceptable salt, solvate, or stereoisomer thereof.

2. The method of claim 1, which further comprises administering to the patient a therapeutically or prophylactically effective amount of at least one second active agent.

3. The method of claim 2, wherein the second active agent is capable of relieving or reducing pain.

4. The method of claim 2, wherein the second active agent is an antidepressant, antihypertensive, anxiolytic, calcium channel blocker, alpha-adrenergic receptor agonist, alpha-adrenergic receptor antagonist, ketamine, anesthetic, muscle relaxant, non-narcotic analgesic, opioid analgesic, anti-inflammatory agent, immunomodulatory agent, immunosuppressive agent, corticosteroid, anticonvulsant, cox-2 inhibitor, hyperbaric oxygen, or a combination thereof.

5. The method of claim 2, wherein the second active agent is salicylic acid acetate, celecoxib, ketamine, gabapentin, carbamazepine, oxcarbazepine, phenytoin, sodium valproate, prednisone, nifedipine, clonidine, oxycodone, meperidine, morphine sulfate, hydromorphone, fentanyl, acetaminophen, ibuprofen, naproxen sodium, griseofulvin, amitriptyline, imipramine or doxepin.

6. The method of claim 1, wherein the pain is nociceptive pain or neuropathic pain.

7. The method of claim 6, wherein the pain is associated with chemical or thermal burn, cut of the skin, contusion of the skin, osteoarthritis, rheumatoid arthritis, tendonitis, or myofascial pain.

8. The method of claim 6, wherein the pain is diabetic neuropathy, post herpetic neuralgia, trigeminal neuralgia, post-stroke pain, complex regional pain syndrome, sympathetic maintained pain syndrome, reflex sympathetic dystrophy, reflex neurovascular dystrophy, reflex dystrophy, spinal cord injury pain, Sudeck atrophy of bone, algoneurodystrophy, shoulder hand syndrome, post-traumatic dystrophy, cancer related pain, phantom limb pain, fibromyalgia, chronic fatigue syndrome, radiculopathy, luetic neuropathy, or painful neuropathic condition induced from a drug.

9. The method of claim 8, wherein the complex regional pain syndrome is type I or type II.

10. The method of claim 8, wherein the painful neuropathic condition is iatrogenically induced by vincristine, velcade or thalidomide.

11. The method of claim 1, wherein the pain is visceral pain, migraine, tension-type headache, post-operative pain, or mixed pain of nociceptive and neuropathic pain.

12. The method of claim 1, wherein the stereoisomer of the immunomodulatory compound is enantiomerically pure.

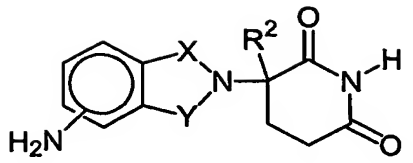
13. The method of claim 1, wherein the immunomodulatory compound is 4-(amino)-2-(2,6-dioxo(3-piperidyl))-isoindoline-1,3-dione.

14. The method of claim 13, wherein the immunomodulatory compound is enantiomerically pure.

15. The method of claim 1, wherein the immunomodulatory compound is 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione.

16. The method of claim 15, wherein the immunomodulatory compound is enantiomerically pure.

17. The method of claim 1, wherein the immunomodulatory compound is of formula (I):

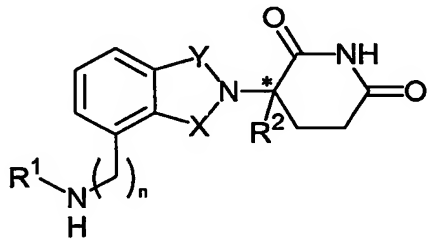


(I)

wherein one of X and Y is C=O, the other of X and Y is C=O or CH_2, and R^2 is hydrogen or lower alkyl.

18. The method of claim 17, wherein the immunomodulatory compound is enantiomerically pure.

19. The method of claim 1, wherein the immunomodulatory compound is of formula (II):



(II)

wherein

one of X and Y is C=O and the other is CH_2 or C=O;

R^1 is H, $(C_1\text{-}C_8)$alkyl, $(C_3\text{-}C_7)$cycloalkyl, $(C_2\text{-}C_8)$alkenyl, $(C_2\text{-}C_8)$alkynyl, benzyl, aryl, $(C_0\text{-}C_4)$alkyl–$(C_1\text{-}C_6)$heterocycloalkyl, $(C_0\text{-}C_4)$alkyl–$(C_2\text{-}C_5)$heteroaryl, $C(O)R^3$, $C(S)R^3$, $C(O)OR^4$, $(C_1\text{-}C_8)$alkyl–$N(R^6)_2$, $(C_1\text{-}C_8)$alkyl–OR^5, $(C_1\text{-}C_8)$alkyl–$C(O)OR^5$, $C(O)NHR^3$, $C(S)NHR^3$, $C(O)NR^3R^{3'}$, $C(S)NR^3R^{3'}$ or $(C_1\text{-}C_8)$alkyl–$O(CO)R^5$;

R^2 is H, F, benzyl, $(C_1\text{-}C_8)$alkyl, $(C_2\text{-}C_8)$alkenyl, or $(C_2\text{-}C_8)$alkynyl;

R^3 and $R^{3'}$ are independently $(C_1\text{-}C_8)$alkyl, $(C_3\text{-}C_7)$cycloalkyl, $(C_2\text{-}C_8)$alkenyl, $(C_2\text{-}C_8)$alkynyl, benzyl, aryl, $(C_0\text{-}C_4)$alkyl–$(C_1\text{-}C_6)$heterocycloalkyl, $(C_0\text{-}C_4)$alkyl–$(C_2\text{-}C_5)$heteroaryl, $(C_0\text{-}C_8)$alkyl–$N(R^6)_2$, $(C_1\text{-}C_8)$alkyl–OR^5, $(C_1\text{-}C_8)$alkyl–$C(O)OR^5$, $(C_1\text{-}C_8)$alkyl–$O(CO)R^5$, or $C(O)OR^5$;

R^4 is $(C_1\text{-}C_8)$alkyl, $(C_2\text{-}C_8)$alkenyl, $(C_2\text{-}C_8)$alkynyl, $(C_1\text{-}C_4)$alkyl–OR^5, benzyl, aryl, $(C_0\text{-}C_4)$alkyl–$(C_1\text{-}C_6)$heterocycloalkyl, or $(C_0\text{-}C_4)$alkyl–$(C_2\text{-}C_5)$heteroaryl;

R^5 is $(C_1\text{-}C_8)$alkyl, $(C_2\text{-}C_8)$alkenyl, $(C_2\text{-}C_8)$alkynyl, benzyl, aryl, or $(C_2\text{-}C_5)$heteroaryl;

each occurrence of R^6 is independently H, (C_1-C_8)alkyl, (C_2-C_8)alkenyl, (C_2-C_8)alkynyl, benzyl, aryl, (C_2-C_5)heteroaryl, or (C_0-C_8)alkyl–C(O)O–R^5 or the R^6 groups join to form a heterocycloalkyl group;

n is 0 or 1; and

* represents a chiral-carbon center.

20. The method of claim 19, wherein the immunomodulatory compound is enantiomerically pure.

21. The method of claim 1, wherein the immunomodulatory compound is a cyano or carboxy derivative of a substituted styrene, 1-oxo-2-(2,6-dioxo-3-fluoropiperidin-3yl) isoindoline, 1,3-dioxo-2-(2,6-dioxo-3-fluoropiperidine-3-yl) isoindoline, or tetra substituted 2-(2,6-dioxopiperdin-3-yl)-1-oxoisoindoline.

22. The method of claim 21, wherein the immunomodulatory compound is enantiomerically pure.

23. A method of treating, preventing, modifying or managing pain, which comprises administering to a patient in need of such treatment, prevention, modification or management a therapeutically or prophylactically effective amount of an immunomodulatory compound, or a pharmaceutically acceptable salt, solvate, or stereoisomer thereof,, before, during or after surgery, psychological or physical therapy directed at reducing or avoiding a symptom of pain in the patient.

24. A pharmaceutical composition comprising an immunomodulatory compound, or a pharmaceutically acceptable salt, solvate, or stereoisomer thereof in an amount effective to treat, prevent, modify or manage pain, and a second active agent capable of relieving or reducing pain.

25. The pharmaceutical composition of claim 24, wherein the second active agent is an antidepressant, antihypertensive, anxiolytic, calcium channel blocker, muscle relaxant, non-narcotic analgesic, anti-inflammatory agent, cox-2 inhibitor, alpha-adrenergic receptor agonist, alpha-adrenergic receptor antagonist, ketamine, anesthetic, immunomodulatory agent, immunosuppressive agent, corticosteroid, hyperbaric oxygen, anticonvulsant, or a combination thereof.

26. The pharmaceutical composition of claim 24, wherein the second active agent is salicylic acid acetate, celecoxib, ketamine, gabapentin, carbamazepine, oxcarbazepine, phenytoin, sodium valproate, prednisone, nifedipine, clonidine, oxycodone, meperidine, morphine sulfate, hydromorphone, fentanyl, acetaminophen, ibuprofen, naproxen sodium, griseofulvin, amitriptyline, imipramine or doxepin.